REMARKS

In the amendments above, Claims 2-4, 5, 8, 10, 11, 14, 61, 63-67, and 78 have been amended, Claims 60, 62, 70, 71, and 77 have been cancelled, and new Claims 79 to 83 have been added, to more particularly point out and distinctly claim Applicants' invention.

In the Office Action, Claims 2-12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Reich et al., U.S. Patent No. 5,962,620 ("Reich"). The Examiner maintains that Reich discloses hydrophilic and hydrophobic polyester polyurethanes; that Reich also discloses that the polyurethanes may be used to form a shape structure or device including tubing, catheters, stents, and the like; that Reich also discloses that hydrophilic polymers may include drugs and enzymes, and may be coated over the polyurethanes; that Reich further discloses encapsulation of drugs in preferably, high viscosity hydrophilic polymers; and that the disclosures of Reich anticipate the claims.

Applicants respectfully traverse the above rejection.

The invention described and claimed herein is directed to an implant for delivering therapeutic agents, which implant comprises a resilient or flexible elastomeric foam matrix scaffold having a hydrophilic coating. It is noteworthy that the scaffold is reticulated, i.e., it comprises interconnected or intercommunicating voids or pores. See, for example, Claims 2 and 79-83. Moreover, the scaffold is at least partially hydrophobic, and the coating contains one or more therapeutic agents to be released within a patient.

As the Examiner pointed out, Reich discloses hydrophilic or hydrophobic polyester polyurethane substrates that may optionally have a coating. However, Reich's substrates differ in that they are either solid or liquid thermoset compositions (see, for example, Column 3, lines 45-46, Column 4, lines 5-14 and 59-61, and Column 5, lines

49-50), not the resilient or flexible reticulated substrates required according to Applicants' invention.

Applicants respectfully suggest that, notwithstanding the Examiner's giving the claims the "broadest most reasonable interpretation," the flexible and resilient compositions claimed herein are different from the compositions taught by Reich. The claimed substrate is a reticulated elastomeric foam matrix scaffold that does not and cannot have the rigidity of Reich's substrates. The fact that the Reich substrates can have a Shore hardness value (see, for example, Col. 6, lines 9-12) is a clear indication of the differences between the substrates claimed herein and Reich's substrates. At best, Reich discloses soft segment engineering to coat other substrates.

Claims 62, 70, and 77 have been identified as potentially being duplicate claims. Each of these claims has been cancelled above.

Claims 77 and 78 have been objected to. Claim 77 has been cancelled, and Claim 78 has been amended.

Claim 2 and dependent Claims 3-12 and 60-78 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner maintains that the specification, while being enabling for hydrophilic coatings, does not reasonably provide enablement for all coatings including hydrophobic coatings, and that the instant specification is not sufficient to support the generic concept of "a coating."

While Applicants do not agree with the Examiner that the specification herein is not enabling for hydrophobic coatings, Claim 2 has been amended to re-insert the term "hydrophilic." It is believed that the amendment to Claim 2 should overcome this rejection.

Claims 3 and 60 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner maintains that the specification, while being enabling for "at least one therapeutic agent contained within the coating," does not reasonably provide enablement for "at least one therapeutic agent is secured to and/or supported by the scaffold" outside of the coating; that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; that the instant specification is not sufficient to support the generic concept of "at least one therapeutic agent is secured to and/or supported by the scaffold"; and that the generic concept of "more than one therapeutic agent is secured to and/or supported by the scaffold" is not supported by the instant specification.

The Examiner's attention is directed to the amendments above, where Claim 3 has been amended and Claim 60 has been cancelled. Claim 3, as amended, specifies that the scaffold comprises at least one therapeutic agent, consistent with Paragraph 186 on page 53. The amendment to Claim 3 and the cancellation of Claim 60 are believed to overcome this rejection.

Claim 4 has been rejected under 35 U.S.C. § 112, first paragraph. The Examiner maintains that the specification, while being enabling for "at least one therapeutic agent is contained within microspheres in the coating", does not reasonably provide enablement for "at least one therapeutic agent contained within microspheres" outside of the coating; that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; and that the instant specification is not sufficient to support the generic concept of "at least one therapeutic agent contained within microspheres".

Claim 4 has been amended above to indicate that the microspheres are in the coating. It is believed that this amendment overcomes the rejection.

Claim 60 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner maintains that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; that there is no teaching of "more than one therapeutic agent"; that the subject matter is not properly described as filed; and that at this time new matter must be considered as part of the claimed subject matter. Cancellation of Claim 60 renders this rejection moot.

Claims 3 and 60 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner maintains that Claim 3 recites the limitation "at least one therapeutic agent is secured to and/or supported by the scaffold," that, however, Claim 2 from which Claim 3 depends includes the limitation "wherein said coating contains one or more therapeutic agents;" and that it is unclear whether the therapeutic agents in Claims 3 and 60 are secured to and/or supported by the scaffold in the coating or if said agent is a separate ingredient outside of the coating.

It is believed that the amendment to Claim 3 above and the cancellation of Claim 60 overcome this rejection.

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner maintains that Claim 4 recites the limitation, "at least one therapeutic agent is contained within microspheres"; that, however, Claim 2 from which Claim 4 depends includes the limitation, "wherein said coating contains one or more therapeutic agents"; and that it is unclear whether the therapeutic agent in Claim 4 is in the microspheres in the coating or if said agent is a separate ingredient found in the microspheres outside of the coating.

It is believed that the amendment to Claim 4 above overcomes this rejection.

Claim 64 recites the limitation "after recovery to a working size and configuration is similar to the original size and shape before compression". The Examiner maintains that there is insufficient antecedent basis for this limitation in the claim.

The Examiner's attention is directed to the amendments above, wherein Claim 64 has been amended to refer to a size and shape before compression. It is believed that this amendment overcomes the rejection of Claim 64.

Claim 78 recites the limitation "the is formed" in the first line of the claim. The Examiner maintains that there is insufficient antecedent basis for this limitation in the claim.

The Examiner's attention is directed to the amendments above, where Claim 78 has been amended to clearly indicate that the scaffold is formed from the polyurethane prepolymer. It is believed that this amendment overcomes the rejection of Claim 78.

Applicants submit that the claims herein, including the newly added claims and the withdrawn claims, are patentable over Reich. Therefore, the rejection under §102 should be withdrawn.

Reconsideration and allowance of all the claims herein are respectfully requested.

Respectfully submitted,

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